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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,394	11/14/2003	Carsten Sjoeholm	10094.210-US	9916
25908 7590 05/28/2008 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER MONSHIPOURI, MARYAM	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 05/28/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/713,394	SJOEHOLM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 27-39 is/are pending in the application.
- 4a) Of the above claim(s) 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-35, 38-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/779,323.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/07 &amp; 11/07 &amp; 2/08</u> .                            | 6) <input type="checkbox"/> Other: _____                          |

Newly presented claims 27-35, 38-39 are still at issue and are present for examination. Claims 36-37 are withdrawn as drawn to nonelected invention.

Applicants' arguments filed on 2/27/08 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-35, 38-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Phrases "identity of at least 90%" in claim 27 (and its dependent claims 28-31), and "identity of at least 95%" in claim 32 (and its dependent claims 33-34) could not be found in any of parent applications. Therefore, considering that instant application is declared to be a continuation, and not a continuation in part, said phrases are considered to be **new matter**. Applicant is reminded to kindly refer applicant to places in the original disclosure wherein said phrases are recited or possibly delete them from the claims.

Claim 35 (and its dependent claims 38-39) remain rejected for claiming a genus of products which have been inadequately described in the disclosure, according to previous office action. In traversal of this rejection applicant argues that he/she has amended claims to recite "at least 90% or 95% identity to SEQ ID NO:1" . However, claim 35 (and its dependent claims 38-39) has not been amended and currently it is unknown how much structural homology or identity exists among the genus of proteases from Nocardiosis protease origin.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-35, 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Oestergaard et al. (WO 01/58276, 8/2001, cited in the IDS). It should be noted that the examiner could not find support for "90% identity "or "95% identity " is any of parent applications. Therefore the earliest filing date that instant claims benefit from is 11/14/2003. In view of said date, Oestergaard teaches and claims a method for improving the nutritional value of an animal feed comprising adding an acid stable protease having 99.5% identity to SEQ ID NO:1 of this invention, having a pH optimum of 8-11 by inherency, wherein the dosage of protease is 0.01-200 mg protease/kg animal feed, anticipating claims 27-35, 38-39 of this invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-35, 38-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bedford et al. (cited previously) in view of Snow-Brand (cited previously) according to previous office action. In traversal of this rejection applicant argues the following : **(1)** that the only experiments using alkaline (and not acid stable ) protease in Bedford et al. are examples 2 and 5 and none of the FCR (feed conversion ratio) values reported in tables 4 and 9 demonstrate a statistically significant improvement of animal feed comprising said protease.

On the other hand Example 4 of this invention displays a statistically significant improvement of protein solubility of SEQ ID NO:1. An artisan would not expect based on Bedford et al. that the proteases recited in present claims would improve the nutritional value of the feed.

**(2)** According to Sjahom's declaration, also filed in parent application, the results of Bedford do not prove to one of ordinary skill that the addition of protease to an animal feed results in an improved FCR. However, surprisingly, the results disclosed in instant application show a significantly better SEQ ID NO:1 solubilization in animal feed leading to improved nutritional value of the feed and such results are totally unexpected.

**(3)** Klunter's declaration, also filed in parent application, describes a set of experiments in which chickens were fed with compositions with or without SEQ ID NO:1

and the results “clearly” demonstrate that broiler chickens have a significantly improved weight gain when fed on feed comprising Nocardiposis protease, which is both unexpected and surprising.

Finally, applicant believes that in view of said surprising and unexpected results the rejection should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. With respect to applicant’s **first** argument it should be noted that Bedford et al. was merely cited to demonstrate that the motivation of improving nutritional value of the feed utilizing proteases was present in the prior art, prior to filing of this application. For argument sake, even if one focused on results obtained by Bedford et al., the fact, raised by applicant, that Bedford et al. do not display a significant improvement of FCR in the presence of its alkaline protease only motivates one of ordinary skill to try to incorporate new proteases (such as acid stable protease of Snow-Brand) into chicken feed in order to obtain better FCR’s, rendering instant invention even more obvious.

With regards to applicant’s **second** argument, he/she is reminded that protein solubility, whether surprisingly and unexpectedly improved or not, in isolation, cannot be automatically translated into improvement of nutritional value of animal feed. As applicant is aware, solubility data should be corroborated with weight gain percentages and FCR values before one can decide its improvement effect on nutritional value of the feed and presently such data is lacking in Sjolholm declaration. Applicant must also remember that instant claims are no longer restricted to utilization of SEQ ID NO:1 but also their homologs for which no declaration or supportive data is provided.

Considering applicant's **third** argument , the point is well taken that some improvement of nutritional value of chicken feed comprising Nocardiosis protease resulting in an increase in broiler chicken weight has been displayed in tables 3A-3B of Klunter's declaration. However, the examiner must remind applicant that (a) said data has only been compared to a chicken feed completely lacking protease and not with a feed that comprises alkaline protease of Bedford. After all, applicant himself/herself in his/her first traversal argument (see above) analyzed Bedford et al. protease feed data in order to discredit its value as prior art. (b) The displayed improvements in Klunter's declaration are hardly significant and unexpected and appear to only demonstrate a minor improvement over feed with no proteases. (c ) Klunter's data again appears to only refer to utilization of SEQ ID NO:1 and not its claimed homologs.

Therefore, in view of the response provided in addition to explanations elaborated in previous office action, the rejection is maintained.

**No claim is allowed.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/  
Primary Examiner, Art Unit 1656

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